# CASE 3

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United States District Court, E.D. Pennsylvania. SMITHKLINE BEECHAM CORPORATION, Smithkline Beecham, P.L.C., Beecham Group, P.L.C. and GlaxoSmithKline, P.L.C.

APOTEX CORPORATION, Apotex, Inc. and TorPharm, Inc.

v

PENTECH PHARMACEUTICALS, INC. and Par Pharmaceuticals, Inc.

SMITHKLINE BEECHAM CORPORATION, Smithkline Beecham, P.L.C. and Beecham Group, P.L.C.

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GENEVA PHARMACEUTICALS, INC. and Sumika Fine Chemicals Co., Ltd. SMITHKLINE BEECHAM CORPORATION, Smithkline Beecham, P.L.C. and Beecham Group, P.L.C.

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ZENITH GOLDLINE PHARMACEUTICALS, INC. and Sumika Fine Chemicals Co., Ltd. SMITHKLINE BEECHAM CORPORATION, Smithkline Beecham, P.L.C. and Beecham Group, P.L.C.

ν.

ALPHAPHARM PTY, LTD. and Sumika Fine Chemicals Co., Ltd.

SMITHKLINE BEECHAM CORPORATION, and Beecham Group, P.L.C.

ANDRX PHARMACEUTICALS, INC., Andrx Pharmaceuticals, L.L.C., BASF Corporation, BASF Pharmachemikalien GMBH & Co. KG and Knoll AG.

SMITHKLINE BEECHAM CORPORATION, and Beecham Group, P.L.C.

v.

TEVA PHARMACEUTICALS USA, INC.
No. 99-CV-4304, 00-CV-4888, 01-CV-0159, 01-CV-2169, 99-CV-2926, 00-CV-5953, 02-CV-1484, 00-CV-1303, 00-CV-6464, 01-CV-2602, 01-CV-1027, 01-CV-3364, 02-CV-8493, 01-CV-2981, 03-CV-6117, 03-CV-3365.

Sept. 28, 2005.

Arthur Makadon, Jamie B. Bischoff, Sally A. Steffen, Ballard Spahr Andrews & Ingersoll, George G. Gordon, Will W. Sachse, Dechert, Price and Rhoads, Ann Kathryn Snyder, Dechert LLP, Philadelphia, PA, Ford F. Farabow, Jr., Richard B. Racine, Robert D. Bajefsky, Walter Y. Boyd. Jr., Finnegan, Henderson, Farabow, Garrett & Dunner, Washington, DC, Kenneth M. Frankel, Reston, VA, for Smithkline Beecham Corporation, Smithkline Beecham, P.L.C., Beecham Group, P.L.C. and Glaxosmithkline, P.L.C.

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Alan H. Bernstein, Robert S. Silver, Caesar Rivise Berstein Cohen & Pokotilow Ltd, Charles S. Marion, Francis P. Devine, III, Pepper Hamilton LLP, Philadelphia, PA, David G. Greene, Deanne M. Mazzochi, Hugh L. Moore, Keith D. Parr, Kevin M. Nelson, Michael J. Gaertner, Paul J. Molino, Richard P. Beem, Sara A. Lufrano, Scott B. Feder, T. Monique Jones, Travis B. Wolfinger, Lord, Bissell & Brook LLP, Chicago, IL, Timothy H. Gilbert, Gilbert's LLP, Toronto, Ontario, for Apotex Corporation, Apotex, Inc. and Torpharm, Inc.

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#### **MEMORANDUM & ORDER**

### SURRICK, J.

\*1 Presently before the Court is Defendants Apotex Corp., Apotex, Inc., And TorPharm, Inc.'s (collectively "TorPharm") Motion To Compel SmithKline Beecham Corporation, Beecham Group, P.L.C., SmithKline Beecham P.L.C., and GlaxoSmithKline, P.L.C. (collectively "SB") To Elect Whether It Intends To Assert Advice Of Counsel Defense Or Be Barred From Raising That Defense (Doc. No. 172, 99-CV-4304; Doc. No. 128, 00-CV-4888; Doc. No. 124, 01-CV-159; Doc. No. 115, 01-CV-2169). For the following reasons, Defendants' Motion will be dismissed as moot.

### I. BACKGROUND [FN1]

FN1. Additional background regarding this litigation and the applicable statutory framework may be found in our Memoranda and Orders dated September 28, 2001, September 30, 2002, October 31, 2002, December 20, 2002, September 29, 2004, and March 31, 2005. (Doc. Nos.50, 71, 77, 85, 165, 182.) Unless otherwise specified, all docket numbers cited in this Memorandum refer to the filings in Civil Action No. 99-4304.

These consolidated cases involve claims of patent infringement made by SB. The patents at issue cover certain forms of paroxetine hydrochloride, processes for making paroxetine hydrochloride, and uses of paroxetine hydrochloride. SB manufactures paroxetine hydrochloride, and then tablets and sells that product in the United States under the trademark Paxil® ("Paxil"). Paxil is an antidepressant drug used to treat a variety of disorders and is one of the most widely prescribed drugs in the United States.

Defendant TorPharm is a generic drug manufacturer that seeks to sell a generic version of Paxil. SB claims that the Defendants' generic products and/or methods of manufacturing the same infringe one or more of SB's patents. In March, 1998, TorPharm became the first generic drug manufacturer to file an

Abbreviated New Drug Application with the United States Food and Drug Administration seeking its approval to market a generic version of Paxil.

On October 23, 2003, TorPharm filed a Second Amended Answer, which included several counterclaims against SB alleging various federal antitrust law and state common law violations. (Doc. 103 .) In responding to TorPharm's counterclaims, SB stated as an affirmative defense that "[t]he Counterclaims are barred, in whole or in part, because at all times, the Counterclaim Defendants have acted in good faith and in furtherance of their legitimate business interests and have caused no injury to competition or to the public." (Doc. No. 170 at 69.) SB also averred that "[t]he Counterclaims are barred because the Counterclaim Defendants' conduct was lawful under the Federal Food, Drug, and Cosmetic Act, the Hatch-Waxman Act, and the Patent Act. (Id. at 70.)

In the instant Motion, TorPharm seeks to require SB to elect whether it "will rely on the advice, conduct, intent or good faith of [Paxil's] manufacturer's inhouse or outside counsel, or any business person who relied on in-house or outside counsel, in defense of [TorPharm's] claims" that "SB illegally hindered TorPharm's ability to market generic paroxetine hydrochloride in competition with SB's Paxil® brand paroxetine hydrochloride in violation of federal antitrust laws and state common laws." (Doc. No. 172 at 1.) TorPharm argues that SB must be required to elect during discovery whether it will assert "advice of counsel" as a defense to its claims that SB acted fraudulently or in bad faith in filing patent litigation against TorPharm. [FN2]

FN2. "A [patent holder] who brings an infringement suit may be subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves (1) that the asserted patent was obtained through knowing and willful fraud within the meaning of Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), or (2) that the infringement suit was a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Nobelpharma Ab v. Implant Innovations, 141 F.3d 1059, 1068 (Fed.Cir.1998) (internal quotations and citation omitted). A party can defend against such a claim by Not Reported in F.Supp.2d Not Reported in F.Supp.2d, 2005 WL 2436662 (E.D.Pa.)

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establishing that it acted upon the advice of counsel in deciding to file an infringement lawsuit.

## II. LEGAL ANALYSIS

\*2 If a defendant raises an advice of counsel defense, it must waive the attorney-client and work-product privileges with respect to that defense. It may not engage in a selective process of waiver. See, e.g., Rhone-Poulenc Rorer, Inc. v. Home Indem. Co., 32 F.3d 851, 863 (3d Cir.1994); see also Trouble v. Wet Seal, Inc., 179 F.Supp.2d 291, 304 (S.D.N.Y.2001) ("[W]hen a party intends to rely at trial on the advice of counsel as a defense to a claim of bad faith, that advice becomes a factual issue, and opposing counsel is entitled to know not only whether such an opinion was obtained but also its content and what conduct it advised." (internal citations and quotations omitted)). Accordingly, a defendant may be required to declare during discovery whether he or she intends to assert an advice of counsel defense at trial in order to permit the plaintiff to pursue discovery on that issue. See, e.g., In re Buspirone Antitrust Litig., 208 F.R.D. 516 (S.D.N.Y.2002).

SB argues that the instant Motion is moot because it has already made its election not to invoke an advice of counsel defense. (Doc. No. 118, No. 01- CV-2169, at 1-4.) It states that:

On September 22, 2004, TorPharm asked whether or not [SB] intended "to raise a 'good faith' or 'reliance on counsel' defense.... [SB] promptly responded that it "sees no need to and has no intention of asserting an 'advice of counsel' defense or otherwise putting at issue the content of any advice it received from counsel in prosecuting, listing, or enforcing the relevant patents." [SB] further advised TorPharm that it "intends to defend itself ... without waiving the application of the attorney-client privilege or work-product doctrine." In sum, [SB] made clear its intent to refute TorPharm's allegations of bad faith, but without invoking its counsel's advice as a defense.

(*Id.* at 3-4 (internal citations omitted).) On October 14, 2004, TorPharm sought greater specificity from SB regarding the advice of counsel issue by asking whether it would rely on such a defense or place such advice at issue regarding: (1) the prosecution of the patents at issue in this case before the United States Patent and Trademark Office; (2) the listing of the patents at issue in this case in the Orange Book; (3) TorPharm's allegation that SB engaged in sham litigation; (4) certain agreements between SB and PAR Pharmaceuticals, Inc. and Pentech

Pharmaceuticals, Inc.; and (5) TorPharm's tortious interference claim. (Doc. No. 172 Ex. I.) In response to TorPharm's queries, SB rested on its prior response regarding the advice of counsel issue. Based on the averments contained in SB's correspondence with TorPharm as well as its pleadings filed with this Court, we are satisfied that SB has made an election not to invoke an advice of counsel defense regarding TorPharm's counterclaims.

In this Circuit, "a party waives the attorney-client privilege by placing the advice of counsel in issue only where 'the client asserts a claim or defense, and attempts to prove that claim or defense by disclosing or describing an attorney-client communication ." [FN3] Fid. & Deposit Co. of Md. v. McCulloch, 168 F.R.D. 516, 520 (E.D.Pa.1996) (quoting *Rhone-*Poulenc, 32 F.3d at 863) (holding that party did not assert an advice of counsel defense and did not place any advice of counsel at issue); see also Aull v. Cavalcade Pension Plan. 185 F.R.D. 618, 630 (D.Colo.1998) ("Waiver of the attorney client or work product privileges can occur when the privilege holder asserts a claim or affirmative defense which puts the privileged matter directly at issue." (citing Rhone-Poulenc, 32 F.3d at 862-64)). In discussing the advice of counsel defense, the Third Circuit has observed that:

<u>FN3.</u> An at issue waiver of the attorney-client privilege also abrogates work-product immunity. *W.L. Gore & Assocs. v. Tetratec Corp.*, Civ. A. No. 89-3995, 1989 U.S. Dist. LEXIS 14245, at \*8 (E.D.Pa. Nov.28, 1989).

\*3 Courts have found that by placing the advice in issue, the client has opened to examination facts relating to that advice. Advice is not in issue merely because it is relevant, and does not necessarily become in issue merely because the attorney's advice might affect the client's state of mind in a relevant matter.

Rhone-Poulenc, 32 F.3d at 863; see also id. at 864 ("Relevance is not the standard for determining whether or not evidence should be protected from disclosure as privileged, and that remains the case even if one might conclude the facts to be disclosed are vital, highly probative, directly relevant or even go to the heart of an issue.").

Thus, a party must take "the affirmative step in the litigation to place the advice of the attorney in issue." *Id.* at 863. This affirmative step requirement is critical:

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Finding a waiver of the attorney client privilege when the client puts the attorney's advice in issue is consistent with the essential elements of the privilege. That is, in leaving to the client the decision whether or not to waive the privilege by putting the attorney's advice in issue, we provide certainty that the client's confidential communications will not be disclosed unless the client takes an affirmative step to waive the privilege, and we provide predictability for the client concerning the circumstances by which the client will waive that privilege. This certainty and predictability as to the circumstances of a waiver encourage clients to consult with counsel free from the apprehension that the communications will be disclosed without their consent.

Id. at 863-64; [FN4] see also Robertson v. Allstate Ins. Co., Civ. A. No. 98-4909, 1999 U.S. Dist. LEXIS 2991, at \*15-16 (E.D.Pa. Mar.10, 1999) (internal citation omitted) (holding that privilege was not waived because party took no affirmative step to place the advice of counsel at issue).

> FN4. Advice of counsel was not raised as an affirmative defense in Rhone-Poulenc, "nor were there any acts evincing a clear intent to waive the attorney-client privilege by placing at issue reliance on the advice of counsel." Glenmede Trust Co. v. Thompson, 56 F.3d 476, 486 (3d Cir.1995).

In this case, SB has not taken an affirmative step to place the advice of counsel at issue. In responding to TorPharm's counterclaims, SB stated as an affirmative defense that "[t]he Counterclaims are barred, in whole or in part, because at all times, the Counterclaim Defendants have acted in good faith and in furtherance of their legitimate business interests and have caused no injury to competition or to the public." (Doc. No. 170 at 69.) Asserting an affirmative defense of good faith does not automatically place advice of counsel at issue. Paul R. Rice, Attorney-Client Privilege in the United States § 9.48, at 182 (2d ed. 1999) ("Only if the defendant elects to offer evidence to disprove the claim, and relies upon the attorney's advice to do so, will the plaintiff be given access to protected communications."). In In re Burlington Northern, Inc., 822 F.2d 518 (5th Cir.1987), the plaintiffs filed an antitrust suit alleging that certain defendant railroads conspired to prevent construction of a coal slurry pipeline by, in part, engaging in sham litigation. In responding to plaintiffs' allegations, defendants contended that their litigation activities could not be construed as a sham and that, as a result, their conduct was protected under Noerr/Pennington doctrine. [FN5] Id. at 521-22. During discovery, plaintiffs argued "that an antitrust defendant who relies on Noerr-Pennington bears the burden of proving the genuineness of his petitioning activities, and, having thus injected his good faith into the case, waives any privilege to documents bearing on that issue." Id. at 533. The Fifth Circuit strongly disagreed, noting that "this is not a case in which a party has asserted a claim or defense that explicitly relies on the existence or absence of the very communications for which he claims a privilege." Id. As such, defendants did not waive any attorney-client or work-product privileges.

> "The Noerr/Pennington doctrine protects 'the right of the people ... to petition the government for a redress of grievances." ' Santana Prods., Inc. v. Bobrick Washroom Equip., Inc., 401 F.3d 123, 131 n. 13 (3d Cir.2005) (quoting U.S. Const. amend. I).

\*4 Two district court decisions reinforce our conclusion. In Cardtoons. L.C. v. Major League Baseball Players Association, 199 F.R.D. 677 (N.D.Okla.2001), plaintiff planned to produce and distribute parody baseball cards. Id. at 679-80. When the defendant argued that this conduct violated its rights and that it would take appropriate action to remedy those violations, plaintiff filed suit. In answering plaintiff's complaint, the defendant asserted two affirmative defenses which averred that it acted in good faith. Specifically, defendant stated that its " 'conduct was in all respects justified and undertaken in good faith in an attempt to protect rights that [defendant] had or reasonably believed it had based on the facts and existing law" ' and that ' '[t]he statements contained in the letters referred to in the Fifth Claim for Relief were true or, in the alternative, were believed by [defendant] in good faith to be true." ' Id. at 682 n. 8 (quoting defendant's answer). The district court concluded that the defendant did not waive any applicable privileges when it averred in its affirmative defenses "that it did not act in bad faith but acted in good faith." Id. at 682. Such pleading was insufficient to constitute an "affirmative act" for the purposes of evaluating whether advice of counsel is placed at issue. Id.

Faced with a similar situation, the court reached the same result in Anderson v. Montgomery Ward & Co., No. 82 C 7277, 1987 WL 5682 (N.D.III. Jan.16, 1987). There, plaintiffs averred that defendant engaged in willful age discrimination. In its answer to that discrimination claim, defendant asserted that it

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acted in good faith. Id. at \*1. Plaintiffs argued that defendant waived any applicable attorney-client privilege by denying plaintiffs' allegations and asserting that it acted in good faith. Id. The court quickly dispatched this argument, explaining that plaintiffs placed defendant's good faith at issue by alleging willful discrimination, and that it could not "force an opposing party to waive the attorney-client privilege ... by alleging willful discrimination and thus placing Ward's good faith in issue." Id. Thus, defendant's "affirmative assertion" of good faith did not waive any applicable attorney-client protection.

Here, SB's denial of TorPharm's bad faith allegations and companion assertion of its good faith conduct does not constitute an affirmative act which supports an at issue waiver. [FN6] It does not assert a defense to TorPharm's counterclaims that explicitly rests on the advice of counsel. (Doc. No. 179 at 69.) Further, SB has not attempted to support any defense by relying on such advice. Thus far, SB has not taken any affirmative act which constitutes an at issue waiver of the attorney-client or work-product privileges. [FN7]

> FN6. TorPharm, in fact, "does not contend that its allegations of bad faith standing alone result in a waiver of SB's privilege or that SB must waive privilege if SB presents any evidence of good faith." (Doc. No. 181 at 7.)

> SB also averred FN7. that "[t]he Counterclaims are barred because the Counterclaim Defendants' conduct was lawful under the Federal Food, Drug, and Cosmetic Act, the Hatch-Waxman Act, and the Patent Act. (Doc. No. 170 at 70.) However, as with the affirmative defense of good faith, merely averring that a party acted in compliance with the law does not automatically place advice of counsel at issue. See Cardtoons, L.C., 199 F.R.D. at 682.

TorPharm contends that "the Court need not decide at this point whether a specific piece of evidence puts advice of counsel into issue or not." (Doc. No. 181 at 16.) We agree. While we conclude that SB has not waived any privileges pursuant to an advice of counsel defense, we do not address the extent to which SB may waive otherwise applicable privileges by relying on certain evidence. At this juncture, we need only emphasize that it is certainly "unfair and contrary to the purpose of the underlying discovery rules to allow defendant to assert a privilege in refusing to comply with discovery requests for information and then to rely on this same information at trial, preventing any effective preparation by opposing counsel." Am. Int'l Airways, Inc. v. Am. Int'l Group, Inc., Civ. A. No. 90-7135, 1991 U.S. Dist. LEXIS 17400, at \*5 (E.D.Pa. Nov. 14, 1991); see also W.L. Gore & Assocs., 1989 U.S. Dist. LEXIS 14245, at \*9. Based on its election not to rely on an advice of counsel defense, SB acknowledges that it "is bound by its representations that it will *not* assert [an advice of counsel] defense.... [Gliven this clear election, any evidence which would fall within such a defense would not trigger the need for additional discovery, because it would properly be excluded by the Court." (Doc. No. 184 at 4 n. 2.)

\*5 SB recognizes that its election prevents it from relying on certain evidence at trial. It states emphatically that it "intends to defend itself against the allegations of bad faith, but without relying on or putting at issue the advice of counsel." (Doc. No. 118, No. 01-CV-2169, at 6.) It "will not attempt to introduce as evidence material that it has withheld from production on the grounds of privilege." (Doc. No. 184 at 6 n. 4.) Moreover, it will not rely on "evidence directly putting at issue the advice of, or communications with, counsel" (id. at 1) and, "in rebutting TorPharm's allegations of bad faith, [SB] will not disclose or describe any attorney-client communications." (Id. at 5.) SB "will not be calling any fact witness, in-house counsel or otherwise, to testify as to attorney-client communications which informed the company's legal basis for any of its conduct in the acquisition, listing and enforcing of the paroxetine patents. Nor will [SB] seek to offer the testimony that it believed particular actions were lawful based on the advice of counsel." (Id. at 10.) We will take SB at its word.

An appropriate Order follows.

#### ORDER

AND NOW, this 28th day of September, 2005, upon consideration of Defendants Apotex Corp., Apotex, Inc., And TorPharm, Inc.'s (collectively TorPharm) Motion To Compel SmithKline Beecham Corporation, Beecham Group, P.L.C., SmithKline Beecham P.L.C., and GlaxoSmithKline, P.L.C. (collectively "SB") To Elect Whether It Intends To Assert Advice Of Counsel Defense Or Be Barred From Raising That Defense (Doc. No. 172, 99-CV-4304; Doc. No. 128, 00-CV-4888; Doc. No. 124, 01-CV-159; Doc. No. 115, 01-CV-2169), it is ORDERED that the Motion is DENIED as MOOT.

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SB has elected to offer no evidence in support of an advice of counsel defense to TorPharm's Counterclaims.

IT IS SO ORDERED.

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